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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,243

12/22/2005

Clara Lucia Garcia-Rodenas

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EXAMINER

GANGLE, BRIAN J

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

05/01/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/562,243	GARCIA-RODENAS ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 12-16, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III in the reply filed on 1/17/2008 is acknowledged.

Claims 1-20 are pending. Claims 1-10, 12-16, and 19-20 are withdrawn as being drawn to non-elected inventions. Claims 11 and 17-18 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed on 7/28/2006 has been considered. An initialed copy is enclosed.

Specification

The use of the trademarks ARASCO and DHASCO have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that the cited occurrences of improper use are only exemplary and applicant should review the specification to correct any other use of trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is rendered vague and indefinite by the phrase "a combination of at least one substance selected from the group consisting of specific fats or non-digestible oligosaccharides,

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associated with a microorganism.” There are multiple issues with the cited phrase. First, it is not clear what is meant by the phrase “specific fats.” It is not clear whether the claim is meant to encompass only particular fats, or if so, which fats. Second, it is not clear what is meant by the term “associated.” It is not clear what type of “association” is necessary to meet the limitations of the claims. Third, it is not clear how one can have a combination of at least one of something. A combination requires more than one, thus the phrase “at least one” is inappropriate. Fourth, it is not clear what is included in the Markush group. Does the group include specific fats, non-digestible oligosaccharides, and microorganisms? Or does the Markush group only include specific fats and non-digestible oligosaccharides? If this is the case, it is not clear why Markush language is needed when the claim seems to require both members of the group. Fifth, it is not clear whether only one or all of the substances are required to be associated with the microorganism (if the microorganism is not part of the Markush group). This rejection affects all dependent claims.

Claim 17 is rendered vague and indefinite by the phrase “comprising the steps of further ensuring an optimal barrier function in infants.” Neither the claims nor the specification provides any means of accomplishing this “step” or determining if it has been accomplished. Furthermore, it is not clear what the goal of this step is. It is not clear whether this limitation is meant to be a step of evaluating the results of the administration of the product, or is it a step where further steps are taken so that optimal barrier function is attained. In addition, the use of the word “an” implies there are multiple barrier functions and that only one needs to be optimized. Therefore, it is not clear what barrier function is to be optimized or how this is to be accomplished.

Claim 18 is rendered vague and indefinite by the phrase “comprising the steps of further reducing the risk of developing allergy and infection.” Neither the claims nor the specification provides any means of accomplishing this “step.” Furthermore, the method requires administration of microorganisms. Thus, in performing the method, one is inducing infection and it is not clear how this can reduce the risk of developing infection.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Haschke *et al.* (WO 01/64225 A1, 2001).

The instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with a microorganism to an infant (claim 11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

Haschke *et al.* disclose a method of administering, to infants, a composition comprising a probiotic organism, non-digestible oligosaccharides, and specific fats (see page 6, lines 10-20; page 5, lines 1-5; page 4, lines 15-25). Although Haschke *et al.* are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Therefore, the disclosure of Haschke *et al.* anticipates the instant claims.

Claims 11 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Giffard *et al.* (WO 03/041512 A1, 5/2003).

The instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with a microorganism to an infant (claim

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11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

Giffard *et al.* disclose a method of administering, to infants, a composition comprising a probiotic organism, prebiotic (non-digestible oligosaccharides), and specific fats (see page 19, lines 1-20; page 18, lines 5-10; page 8, lines 15-25; page 7, lines 25-30). Although Giffard *et al.* are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Therefore, the disclosure of Giffard *et al.* anticipates the instant claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Shanon A. Foley/
Supervisory Patent Examiner, Art Unit 1645